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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,422	08/04/2000	Berton Gunter	MERK-0004/20671	1928

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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,422

Applicant(s)

GUNTER, BERTON

Examiner

Mary K Zeman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003 and 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-58 is/are pending in the application.
- 4a) Of the above claim(s) 10-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/03 has been entered.

Claims 1, 2, and 4-58 are pending in this application. Claims 10-58 remain withdrawn from consideration as being drawn to a non-elected invention.

Applicant's arguments filed 10/24/03 have been fully considered but they are not persuasive. Any rejection not repeated below has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by French et al. (USP 6,297,018).

The claims are drawn to methods of evaluating data generated by performing a high throughput assay in a three dimensional array, wherein the data is compensated for positional and systematic effects, scored and formatted. This formatting then allows for the identification of a biologically active agent in the assay.

French et al. (USP 6,297,018) discloses automated high throughput screening assays for active biological agents. French et al use the common three-dimensional array in the assays, and

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use the arrays to screen for biologically active agents in a collection of test agents. Figure 12 shows a common reader for a three dimensional array, and an array in place. The assay and array are subject to systemic and positional effects. Figures 16-25 show the row and column aspects of the arrays, which indicate the data therefrom also contains row and column aspects. Columns 39-47 discuss in detail the physical aspects of the arrays, noting their geometry, and how that geometry and the positions of the wells can influence the data obtained. French et al. then discuss in great detail at columns 47-70 how to compensate the raw assay data for systematic (background) and positional (edge, meniscus, position of detector in the well etc.) effects, how to score the compensated data, how to format it accordingly, and how to use it to identify biologically active agents by identifying data points that statistically deviate from other points in the formatted scored data.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over French et al. as applied to claims 1, 2 and 4-6 above, in view of MATHSOFT.

The claims are drawn to methods of evaluating data generated by performing a high throughput assay in a three dimensional array, wherein the data is compensated for positional and systematic effects, scored and formatted. This formatting then allows for the identification of a biologically active agent in the assay. Claims 7-9 specifically speak to assessing row and column based effects.

French et al. (USP 6,297,018) discloses automated high throughput screening assays for active biological agents. French et al use the common three-dimensional array in the assays, and use the arrays to screen for biologically active agents in a collection of test agents. Figure 12 shows a common reader for a three dimensional array, and an array in place. The assay and

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array are subject to systemic and positional effects. Figures 16-25 show the row and column aspects of the arrays, which indicate the data therefrom also contains row and column aspects. Columns 39-47 discuss in detail the physical aspects of the arrays, noting their geometry, and how that geometry and the positions of the wells can influence the data obtained. French et al. then discuss in great detail at columns 47-70 how to compensate the raw assay data for systematic (background) and positional (edge, meniscus, position within the well, etc.) effects, how to score the compensated data, how to format it accordingly, and how to use it to identify biologically active agents by identifying data points that statistically deviate from other points in the formatted scored data.

While French et al. implicitly disclose the compensation for row and column based effects on the raw assays data, it is not addressed as such in the specification.

As set forth throughout the specification, the MATHSOFT program S-PLUS allows for the analysis of raw data and offers the ability to transform that raw data according to the end use of the data. At page 12 of the specification, the following is set forth: "Commercially available statistical software may be employed to implement many of the functions of the algorithm of the present invention. Such software may for example include S-PLUS statistical data analysis software, produced and/or marketed by MATHSOFT, Inc. of Cambridge, Massachusetts... Examples of S-PLUS code written for the S-PLUS software and employed to implement the positionally correcting algorithm are set forth in the attached appendix." This indicates that it is the commercially available and acknowledged prior art of the S-PLUS software that is used in the invention. The limitations of the above rejected claims do not require any new, novel or unobvious steps not set forth in the S-PLUS software. The specification and appendix merely choose various functions from known and commercially available software, and align them to perform a certain task. For example, at pages 14, lines 9-10, page 15, lines 4-5, and 25-27, page 16, lines 27-29, page 17, lines 10-17, and page 18 lines 10-13, lines 17-30, (among others) the specification repeatedly points out that various features are either well known in the art, or provided by the S-PLUS software.

The difference between the prior art and the claimed invention of claims 7-9 is the recited data sources. These data sources are descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or

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modify those data using a series of processing steps that do not impose a change on the processing steps and are thus nonfunctional descriptive material. The claimed invention uses known software to solve a known problem in a conventional manner. See pages 12-30 of the specification acknowledging known prior art computer assisted data analysis and modification techniques used in the methods set forth therein. Neither the specification, nor the claims set forth any special, non-obvious modifications to the known, conventional software and method steps. A method of using a known program (e.g. S-PLUS known in the prior art to MATHSOFT) for its known purpose to compare and modify data sets does not become non-obvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the well known MATHSOFT S-PLUS software in the compensation and correction of well known row and column effects in microarray data analysis. One of skill in the art would have been motivated to use such software as it easily works with data in row/column format and performs all of the necessary compensation, formatting and scoring function algorithms.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272-0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
2/27/04


MARY K. ZEMAN
PRIMARY EXAMINER

2/16/31